Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Krystexxa® (pegloticase)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:

Krystexxa (pegloticase) is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients who are refractory to conventional therapies such as NSAID's, glucocorticoids, and colchicine.

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors (e.g., allopurinol, febuxostat) at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Krystexxa (pegloticase) is not recommended for the treatment of asymptomatic hyperuricemia.

Gout is a common arthritis caused by deposition of monosodium urate crystals within joints that can also deposit in tissues and the kidneys. Chronic hyperuricemia is the most important risk factor for gout; although asymptomatic hyperuricemia is common, many people never develop gout.

Acute gouty arthritis most commonly presents as an excruciating attack of pain at night involving a single joint in the lower extremity. Inflammation of the first metatarsophalangeal joint is classically termed podagra. Without treatment the initial acute gout attack generally resolves within a few days. Subsequent attacks frequently last longer and may spread to the upper limbs. Gout usually presents as a monoarthritis of the lower extremities, with pain, erythema, and swelling of the joints.

Diagnosis of gout is based on symptom presentation and confirmed by the presence of monosodium urate crystals upon aspiration of synovial joint fluid. Despite low mortality associated with gout, untreated acute attacks can lead to chronic tophaceous gout characterized by tophi, chronic polyarticular involvement with low-grade joint inflammation, and joint deformity. Studies have also linked hyperuricemia with comorbidities such as hypertension, obesity, renal disease, metabolic syndrome, and cardiovascular.

Goals of treatment for gout include symptom control during an acute attack, risk factor modification, and pharmacotherapy to prevent recurrent attacks and chronic sequela. There is consensus that achievement and maintenance of serum uric acid (SUA) levels below the limit of urate solubility in extracellular fluids is necessary for long-term treatment success in patients with persistent or progressive gout. The accepted goal range of SUA for maintenance in clinical studies and evidence-based

guidelines is less than 6 mg/dL.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Krystexxa (pegloticase) for members, when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic gout refractory to conventional therapy meeting at least one of the following criteria:
    a. Three (3) or more flares within the past 18 months
    b. One or more tophi
    c. Chronic gouty arthritis

AND

2. Documented baseline serum uric acid level of more than 6 mg/dL

AND

3. The prescribing physician is a rheumatologist

AND

4. The Member has failed to achieve adequate symptom control after an adherent trial of drugs listed in both **a and b** below, prescribed at the maximum therapeutic dose for a period of at least **three (3)** months, unless clinically inappropriate, contraindicated, or intolerant
    a. Allopurinol or febuxostat (Uloric)
    b. Probenecid (alone or in combination with allopurinol or febuxostat)

AND

5. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies

Limitations

- The Plan does not cover Krystexxa (pegloticase) for asymptomatic hyperuricemia.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2507	Injection, pegloticase, 1 mg

References:

1. Baraf HS, Becker MA, Gutierrez-Urena SR, et al. Tophus burden reduction with pegloticase : results from phase 3 randomized trials and open-label extension in patients with chronic gout refractory to conventional therapy. Arthritis Res Ther. 2013 Sep 26;15(5):R137.
2. Becker MA, Baraf HS, Yood RA, et al. Long-term safety of pegloticase in chronic gout refractory to conventional treatment. Ann Rheum Dis. 2013 Sep 1;72(9):1469-74.
3. Chohan S, Becker MA. Update on emerging urate-lowering therapies. Curr Opin Rheumatol 2009; 21:143-149.
4. Conway N, Schwartz S. Diagnosis and management of acute gout. Med Health RI 2009; 92(11):356-358.
5. Eggebeen AT. Gout: an update. Am Fam Physician. 2007; 76(6):801-8.
6. Krystexxa (pegloticase) [package insert]. Lake Forest, IL: Horizon Pharma Rheumatology LLC; August 2023.
7. Richette P, Bardin T. Gout. Lancet. 2010; 375(9711):318-328.
8. Krystexxa™ (Pegloticase). Hayes Updates. Last updated September 2010. Accessed online February 23, 2022 at https://evidence.hayesinc.com/report/pg.165.
9. Pharmacologic urate-lowering therapy and treatment of tophi in patients with gout. UpToDate. Wolters Kluwer. Last updated December 16, 2020. Accessed online February 23, 2022 at https://www.uptodate.com/contents/pharmacologic-urate-lowering-therapy-and-treatment-of-tophi-in-patients-with-gout?source=history_widget.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Administrative updates to add Medical Benefit Drugs to title and update MATogether and RITogether fax numbers to 617-673-0939 (effective 12/1/23).
- November 12, 2024: No changes

- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 2025 E-Vote: no change (effective 1/1/2026)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.